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NEUROSURGICAL SERVICES

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Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher's Lane, Rm 1061
Rockville, Maryland 20852

Re: Docket 97N-484S

To Whom It May Concern:

I wish to comment on the implication of a proposed FDA regulation that appeared in the September 30, 1999 issue of the Federal Register. The wording used in this regulation, if accepted, could allow the FDA to regulate some types of allograft as medical devices.

As I routinely use bone as tissue from a bone bank, the implication of a curtailed supply of bone products associated with the proposal above are staggering. I have relied on allograft use of bone dowels in a significant number of surgical cases yearly for many years. The thought of curtailing the supply of this tissue would increase the cost of patient care with respect to its use. I believe the indiscriminate use of "hardware" is not to be condoned, and would foresee further use of such hardware in the absence of the bone tissue as currently utilized. The other option is to use autograft bone, which is no better than the allograft in the long run, and increases the length of hospitalization and morbidity associated with its use as a donor tissue.

Sincerely,

Thomas A. Carlstrom, M.D.

TAC:lrh

97N-484S

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A multi-specialty clinic serving Iowa

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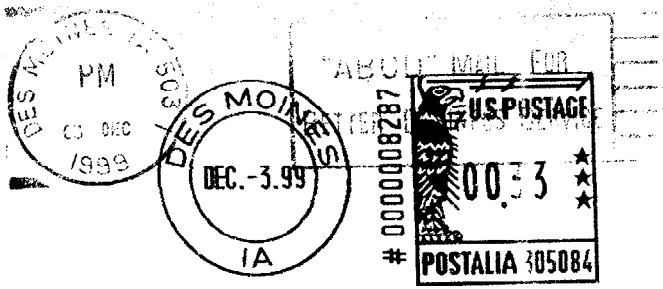

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